IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	
Inventors: Elizabeth Moyer et al.	**Group Art Unit: 1645**
Serial No.: 09/393,590	Examiner: Sarvamangala Devi
Filed: September 9, 1999	
Title: Stable Liquid Formulations of Botulinum Toxin	ELECTRONICALLY FILED ON JUNE 6, 2006

Request for Supervisory Review of Finality of Action

or Alternatively

Petition Under 37 C.F.R. 1.181 for Review of the Finality of Rejection

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Introductory Comments:

It is respectfully requested that supervisory review be made of the propriety of the finality of the Office Action mailed December 8, 2005. Alternatively, if required, please treat this request as a petition under 37 CFR 1.181 for review of the finality of the Office Action mailed December 8, 2005, and set aside the Advisory Action mailed May 12, 2006, and enter the amendments to the claims in the Response to Final Office Action filed May 5, 2006.

Remarks begin on page 2 of this paper.

Remarks:

A review of the amendment of September 13, 2005 shows that several changes were made to the claims:

- "stable" was changed to "stabilized"
- "for therapeutic use in humans" was added to describe the formulation
- "to the formulation" was added for the buffering range
- "a therapeutic concentration suitable for use in humans" was inserted
- and "capable of being" was added before "stable" and "when stored" was added before "for at least one year"

These changes were made for clarity and do not significantly change the clear meaning of the claims previously presented. Since the previous claims already recited a pharmaceutical formulation, a therapeutic concentration is assumed but for clarity, such limitation was added. "Buffered saline" was already a limitation present in the claims. The focus by the examiner of "buffered saline" versus "saline" is not understood since "buffered saline" was not newly added.

In paragraph 22 of the final office action, the Examiner walks through the newly added limitations and essentially dismisses each limitation as being an intended use, a functional limitation, without actual recited dosages or concentrations or without any degree of retention of potency. The Examiner thus indicates that these added limitations do not limit the claims in any significant manner that affects the interpretation of the claims as compared to the prior art.

Thus, since the Examiner has discounted all the limitations which were added, it cannot be argued that the limitations necessitated the application of new prior art or a new ground of rejection. Since these limitations are not deemed to materially change the claims, this prior art could have been applied and these rejections could have been made in the first office action. This prior art could have been applied to the claims with or without the added limitations and thus the final rejection is inappropriate, premature and should be withdrawn.

Applicants requested reconsideration of the finality of the rejection when presenting the amendment in the Response After Final Office Action filed May 5, 2006. The Examiner provided detailed explanations of why the amendment would not be entered but did not address any of the rebuttals to the grounds of rejection or the arguments made by applicants, including the argument that the finality was premature. While an extensive rebuttal is not expected, a brief set of remarks in response to applicants arguments are typically expected and especially an explanation of why the request for reconsideration of the finality of the previous office action was expected and would seem to be required. With respect to the appealable issues, the Examiner provided no rebuttal or brief explanation of why these arguments were not convincing to allow the applicants to appeal the rejections should that be necessary.

Applicants, via their counsel, requested an interview to discuss the issues herein, and the Examiner has refused to grant such an interview.[1]

Applicants appreciate the thorough review of the application provided by the Examiner but believe that under the present facts the finality of the Office Action is premature, as well as the rejections of record.

Applicants request supervisory review of the facts in this application and requests that the finality of the action be withdrawn, the action designated as a non-final rejection and the amendment after final be entered and considered by the examiner.

Should the Supervisor have any questions, the Supervisor is encouraged to telephone the undersigned.

[1] The Examiner has provided her account of telephone conversations with counsel for Applicants (Ray Akhavan, Reg No. 58,120, and an associate in the firm of Wilson Sonsini Goodrich & Rosati, attorneys of record in this application). The Examiner's account of these conversations is inaccurate and incorrect in many instances. Attached hereto is "Applicant's Record of Inteview" signed by Mr. Akhavan.

The Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to Deposit Account No. 23-2415 (Attorney Docket No.31242.701.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Date: June 6, 2006

By: Albert P. Halluin
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Palo Alto, CA 94304
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Customer No. 021971

Applicant's Record of Interview

The following is the undersigned's recollection of what was discussed during telephone conversations with the Examiner as outlined below.

Interview Summary 1, May 16, 2006:

Examiner Devi was contacted, and it was expressly acknowledged that while it is entirely within her discretion, a personal interview was sought to move prosecution forward. Examiner Devi indicated that the Advisory Action provided a detailed response to each of the arguments set forth in the Remarks filed after-final. The Examiner inquired what was specifically sought to be discussed in the personal interview.

It was expressly indicated to the Examiner that the Advisory Action was not yet available on Private Pair, but it was earnestly believed that the after-final amendments at least distinguish over the art rejections of record. In particular, it was indicated that the limitation "ready-to-use" was sought to be discussed and how such a limitation distinguishes the invention and places the claims in better -condition for allowance or appeal. Examiner Devi acknowledged that the limitation did distinguish the invention over the art rejections of record, but further indicated that as such an interview is after-final, she could only provide a limited amount of time for discussion. Examiner Devi indicated that she was not allotted any additional time for prosecution of this application, but she indicated that she would grant the interview.

Subsequently, Examiner Devi left a voice message indicating that since Mr. Akhavan was not listed as an attorney of record, that an Associate Power of Attorney would be required. In reply a voice message for the Examiner, Mr. Akhavan indicated that according to the PTO guidelines and rules, Associate Powers of Attorney are no longer required, because as long as an attorney certifies that he/she is authorized to represent a client (i.e., with a signature and registration number), then there is no need for an Associate Power of Attorney.

Interview Summary 2, May 17, 2006:

Examiner Devi telephoned Mr. Akhavan and - read- through the provisions in the MPEP dealing with attorney representations before the Office. She then acceded that an attorney could

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represent a client and attest to authorization to do so by providing a signature with the corresponding registration number. The Examiner indicated that she would not provide any of the Office's files/documents associated with this application for the attorney's review, to which Mr. Akhavan indicated that no such files would be required for the interview.

Subsequently, Examiner Devi indicated that as this request was after-final a written agenda for what is sought to be discussed would be required, and that it is entirely within the Examiner's discretion to allow interviews after-final.

Mr. Akhavan indicated that the finality of the previous action, as set forth in Remarks submitted to the Office, could be another topic for discussion, as it appears the Advisory Action did not address this argument. Examiner Devi indicated that if Applicant disagrees with any assertions in the Advisory Action then Applicant is free to file a response or petition. Mr. Akhavan indicated that there was no need for a petition if the Examiner would allot 30 minutes to review the salient points not addressed in the Advisory action.

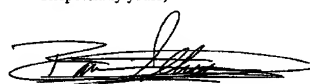
Examiner Devi responded that as this was an after-final request, she would require a written request of what would be discussed, to which Mr. Akhavan indicated that he would submit such a written request if so required.

On May 19, 2006, a facsimile (Appendix A) was sent to the Examiner, outlining what was sought to be discussed including finality of the previous Office Action being improper.

Interview Summary May 22, 2006:

The Examiner left a voice message indicating that the interview would not be granted as all issues have been adequately addressed in the Advisory Action.

Respectfully yours,



Ramin Akhavan, Reg. No. 58,120
WILSON SONSINI GOODRICH & ROSATI, P.C.

Appendix A

Dear Examiner Devi:

Pursuant to your request, the following provides an outline for what is sought to be discussed in the interview next week:

1. Finality of the previous Office Action.
2. Non-entry of the After-Final Amendments.
3. Implications of After-Final Amendments on rejections of record.
4. Considerations for rejections under § 112.

It is very much appreciated that you are granting this opportunity to discuss certain issues, which if resolved, will move prosecution forward in a positive manner. Further, it is earnestly believed that items 1-4 above present valid issues for reconsideration, which were set forth in the response after-final.

If you should have any questions or concerns about the outlined agenda, please feel free to contact me, at 703-734-3132. Thanks again.

Very truly yours,

/s/
Ray Akhavan
Reg. No. 58,120
Wilson Sonsini Goodrich & Rosati, P.C.